



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 524

[Docket No. FDA-2013-N-0002]

New Animal Drugs; Change of Sponsor; Fentanyl; Iron Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two approved new animal drug applications (NADAs) from Alstoe, Ltd., Animal Health, to Sogeval S.A., and a change of sponsor for an NADA from Nexcyon Pharmaceuticals, Inc. to Elanco Animal Health, A Division of Eli Lilly & Co.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8300, email: steven.vaughn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Alstoe, Ltd., Animal Health, Pera Innovation Park, Nottingham Rd., Melton Mowbray, Leicestershire, England LE13 0PB has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 099-667 for IMPOSIL (iron dextran complex) Injection and NADA 110-399 for GLEPTOSIL (gleptoferron) Injection to Sogeval S.A., 200 Avenue de Mayenne, 53000 Laval, France. Nexcyon Pharmaceuticals, Inc., 644 W. Washington Ave., Madison, WI 53703 has informed FDA that it has transferred

ownership of, and all rights and interest in, NADA 141-337 for RECUVYRA (fentanyl) Transdermal Solution to Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285. Accordingly, the Agency is amending the regulations in 21 CFR parts 522 and 524 to reflect the transfers of ownership.

Following these changes of sponsorship, Alstoe, Ltd., Animal Health, and Nexcyon Pharmaceuticals, Inc., are no longer sponsors of approved NADAs. Accordingly, FDA is amending 21 CFR 510.600 to remove the entries for these firms.

In addition, Sogeval S.A. is now a sponsor of approved NADAs. Accordingly, FDA is amending 21 CFR 510.600 to add entries for this firm.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 522 and 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 522, and 524 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In the table in paragraph (c)(1) of § 510.600, remove the entries for "Alstoe, Ltd., Animal Health" and "Nexcyon Pharmaceuticals, Inc.", and alphabetically add an entry for "Sogeval S.A."; and in the table in paragraph (c)(2), remove the entries for "050929" and "062408", and numerically add an entry for "059120" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Sogeval S.A., 200 Avenue de Mayenne, 53000 Laval, France	059120
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
059120	Sogeval S.A., 200 Avenue de Mayenne, 53000 Laval, France
* * * * *	

PART 522--IMPLANTATION OR INJECTBLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1182 [Amended]

4. In § 522.1182, in paragraphs (b)(3) and (b)(8), remove "062408" and in its place add "059120".

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.916 [Amended]

6. In paragraph (b) of § 524.916, remove "050929" and in its place add "000986".

Dated: July 17, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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